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EXAMINER

TOMASZEWSKI, MICHAEL

ART UNIT PAPER NUMBER

3626

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/864,926	<b>Applicant(s)</b> NG ET AL.	
	<b>Examiner</b> Mike Tomaszewski	<b>Art Unit</b> 3626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Notice To Applicant***

1. This communication is in response to the amendment filed 6/22/06 and the RCE on 8/1/06. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/1/06 has been entered. Claims 1-38 have been canceled. Claims 39, 43, 45, and 47 have been amended. Claims 39-47 are pending.

### ***Specification***

2. The new matter objection is hereby withdrawn due to the amendment filed on 6/22/06 and the RCE filed on 8/1/06.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fletcher-Haynes et al. (US 2001/0034614; hereinafter Fletcher-Haynes), in view of Stevens et al. (6,428,640; hereinafter Stevens), and in view of Official Notice.

- (A) As per currently amended claim 39, Fletcher-Haynes discloses a method of configuring a blood component collection instrument comprising the steps of:

- (1) collecting a biological characteristic of a donor (Fletcher-Haynes: par. [0086]; Fig. 2C, 2D and 3C);
- (2) calculating a nomogram by utilizing the biological characteristic of the donor (Fletcher-Haynes: par. [0127] and [0296]; Fig. 3C and 9A-10)

(As per nomograms, Examiner takes Official Notice that nomograms and the technique of utilizing them to graphically make, *inter alia*, calculations

and estimations are notoriously well known and obvious and were developed and used well prior to Applicant's invention. For example, nomograms have routinely been used in stereology to make predictions about how much sampling is required to obtain a given coefficient of error. Nomograms have also routinely been used in blood collection procedures to estimate, *inter alia*, blood volumes. As such, the recitations pertaining to nomograms in the instant application are deemed to be insufficient to overcome the prior art.);

- (3) transmitting the nomogram to a blood component collection instrument (Fletcher-Haynes: par. [0012]);
- (4) selecting a blood component collection application in response to the nomogram, the blood component collection application defining at least a portion of a blood component collection process (Fletcher-Haynes: par. [0012], [0057] and [0059]); and
- (5) loading the selected blood component collection application wherein the blood component collection instrument is configured for the blood component collection process involving the donor (Fletcher-Haynes: par. [0014] and [0015]; Fig. 6A).

Fletcher-Haynes, however, fails to *expressly* disclose a method of configuring a blood component collection instrument comprising the steps of:

- (6) scanning identification code associated with the blood component collection kit; and
- (7) determining from the scanned identification code whether a blood component collection kit is compatible with the selected blood component collection application.

Nevertheless, these features are old and well known in the art, as evidenced by Stevens. In particular, Stevens discloses a method of configuring a blood component collection instrument comprising the steps of:

- (6) scanning identification code associated with the blood component collection kit (Stevens: col. 4, line 63-col. 5, line 17); and
- (7) determining from the scanned identification code whether a blood component collection kit is compatible with the selected blood component collection application (Stevens: col. 4, line 63-col. 5, line 17).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Stevens with the combined teachings of Fletcher-Haynes and Official Notice with the motivation of ensuring that compatible materials are utilized for a particular blood collection procedure.

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Official Notice with the combined teachings of Fletcher-Haynes and Stevens with the motivation of graphically approximating blood collection calculations.

(B) As per previously presented claim 40, Fletcher-Haynes discloses the method of claim 39 further comprising the steps of:

- (1) providing a memory being capable of storing a plurality of blood component collection applications (Fletcher-Haynes: par. [0012]); and
- (2) providing a server for running the blood component collection process, the server being operably connected to the blood component collection instrument and the memory (Fletcher-Haynes: par. [0012]).

(C) As per previously presented claim 41, Fletcher-Haynes discloses the method of claim 40 further comprising the steps of:

- (1) providing a management interface for transmitting the nomogram to the system server (Fletcher-Haynes: par. [0059]); and
- (2) determining if an operator of the blood component collection instrument is qualified for the selected blood component collection application (Fletcher-Haynes: par. [0074], [0079], [0114], [0120] and [0132]).

(D) As per previously presented claim 42, Fletcher-Haynes discloses the method of claim 40 further comprising the steps of:

- (1) providing an identifier for the donor (Fletcher-Haynes: par. [0167]);
- (2) associating the nomogram with the donor identifier (Fletcher-Haynes: par. [0127]; Fig. 3B and 3C); and
- (3) storing the nomogram in the memory (Fletcher-Haynes: par. [0127]; Fig. 3C).

(E) As per currently amended claim 43, Fletcher-Haynes discloses a method of configuring a blood component collection instrument comprising the steps of:

- (1) providing a blood component collection application defining at least a portion of a blood component collection process (Fletcher-Haynes: par. [0012];
- (2) providing a memory being capable of storing a plurality of blood component collection applications (Fletcher-Haynes: par. [0012]);
- (3) collecting a biological characteristic of a donor (Fletcher-Haynes: Fig. 2C, 2D and 3C);



Art Unit: 3626

- (4) calculating a nomogram by utilizing the biological characteristic of the donor, the donor having an identifier (Fletcher-Haynes: par. [0127] and [0296]; Fig. 3C and 9A-10);
- (5) associating the nomogram with the donor identifier (Fletcher-Haynes: par. [0127]; Fig. 3B and 3C);
- (6) storing the donor identifier in the memory (Fletcher-Haynes: par. [0057]);
- (7) transmitting the donor identifier to the blood component collection instrument (Fletcher-Haynes: par. [0057]);
- (8) retrieving the nomogram associated with the donor identifier (Fletcher-Haynes: par. [0127]; Fig. 3B and 3C);
- (9) selecting a blood component collection application in response to the nomogram (Fletcher-Haynes: par. [0012], [0057] and [0059]);
- (10) loading the selected blood component collection application (Fletcher-Haynes: par. [0057]);
- (11) providing a server for running the blood component collection process, the server being operably connected to the blood component collection instrument and the memory (Fletcher-Haynes: par. [0012]).

Fletcher-Haynes, however, fails to *expressly* disclose a method of configuring a blood component collection instrument comprising the steps of:

Art Unit: 3626

- (12) scanning an identification code associated with the blood component kit;  
and
- (13) determining from the scanned identification code whether a blood component collection kit is compatible with the selected blood component collection application.

Nevertheless, these features are old and well known in the art, as evidenced by Stevens. In particular, Stevens discloses a method of configuring a blood component collection instrument comprising the steps of:

- (12) scanning an identification code associated with the blood component kit  
(Stevens: col. 4, line 63-col. 5, line 17); and
- (13) determining from the scanned identification code whether a blood component collection kit is compatible with the selected blood component collection application (Stevens: col. 4, line 63-col. 5, line 17).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Stevens with the combined teachings of Fletcher-Haynes and Official Notice with the motivation of ensuring that compatible materials are utilized for a particular blood collection procedure.

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Official Notice with the combined teachings of

Art Unit: 3626

Fletcher-Haynes and Stevens with the motivation of graphically approximating blood collection calculations.

(F) As per previously presented claim 44, Fletcher-Haynes discloses the method of claim 43 further comprising the step of:

- (1) providing a management interface for transmitting the nomogram to the system server (Fletcher-Haynes: par. [0059]); and
- (2) determining if an operator of the blood component collection instrument is qualified for the selected blood component collection application (Fletcher-Haynes: par. [0074], [0079], [0114], [0120] and [0132]).

(G) As per currently amended claim 45, Fletcher-Haynes discloses a system for configuring a blood component collection instrument, the blood component collection instrument being operably connected in a blood component collection facility for collecting a blood component from a donor, the system comprising:

- (1) a nomogram calculated from at least one biological characteristic of a donor (Fletcher-Haynes: par. [0127] and [0296]; Fig. 3C and 9A-10);
- (2) a blood component collection application defining at least a portion of a blood component collection process (Fletcher-Haynes: par. [0012]);

- (3) a system server being operably connected to the blood component collection instrument, the system server running the blood component collection application, the blood component collection application being selected in response to the nomogram wherein the blood component collection instrument is configured for the blood component collection process from the donor (Fletcher-Haynes: par. [0012], [0057], and [0059]); and
- (4) a memory being operably connected to the system server, the memory for storing the blood component collection application (Fletcher-Haynes: par. [0012]).

Fletcher-Haynes, however, fails to *expressly* disclose a system for configuring a blood component collection instrument, the blood component collection instrument being operably connected in a blood component collection facility for collecting a blood component from a donor, the system comprising:

- (3) a blood component collection kit with an identification code, said identification code used to determine if the blood component collection kit is compatible with the selected blood component collection application.

Nevertheless, these features are old and well known in the art, as evidenced by Stevens. In particular, Stevens discloses a system for configuring a blood component

collection instrument, the blood component collection instrument being operably connected in a blood component collection facility for collecting a blood component from a donor, the system comprising:

- (3) a blood component collection kit with an identification code, said identification code used to determine if the blood component collection kit is compatible with the selected blood component collection application (Stevens: col. 4, line 63-col. 5, line 17).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Stevens with the combined teachings of Fletcher-Haynes and Official Notice with the motivation of ensuring that compatible materials are utilized for a particular blood collection procedure.

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Official Notice with the combined teachings of Fletcher-Haynes and Stevens with the motivation of graphically approximating blood collection calculations.

(H) As per previously presented claim 46, Fletcher-Haynes discloses the system of claim 45 further comprising:

a reader for entering the nomogram, the reader being operably connected to the system server wherein the nomogram is associated with the donor (Fletcher-Haynes: par. [0022] and [0071]).

(l) As per currently amended claim 47, the Fletcher-Haynes discloses a medium readable by a programmable device, the medium for use in a system having an operating interface for managing a blood component collection facility comprising a blood component collection instrument and a system server, the system server having a memory and being operably connected to the blood component collection instrument, the blood component collection instrument being capable of self-configuring the blood component collection instrument in response to a nomogram received by the system server, the nomogram being calculated in response to a biological characteristic of an identified donor, the medium comprising:

- (1) a first segment for receiving the nomogram (Fletcher-Haynes: par. [0127]; Fig. 3C);
- (2) a second segment for selecting a blood component collection application in response to the nomogram (Fletcher-Haynes: par. [0012], [0057] and [0059]);
- (3) a third segment for loading the blood component (Fletcher-Haynes: Fig. 3D); and

- (4) a fifth segment for configuring the blood component collection instrument in response to the blood component collection application, the configured blood component collection instrument being ready for blood component collection from the donor (Fletcher-Haynes: par. [0014]).

Fletcher-Haynes, however, fails to *expressly* disclose a medium readable by a programmable device, the medium for use in a system having an operating interface for managing a blood component collection facility comprising a blood component collection instrument and a system server, the system server having a memory and being operably connected to the blood component collection instrument, the blood component collection instrument being capable of self-configuring the blood component collection instrument in response to a nomogram received by the system server, the nomogram being calculated in response to a biological characteristic of an identified donor, the medium comprising:

- (5) a fourth segment for determining if a scanned identification code associated with a blood component collection kit is compatible with the selected blood component collection application.

Nevertheless, these features are old and well known in the art, as evidenced by Stevens. In particular, Stevens discloses a medium readable by a programmable device, the medium for use in a system having an operating interface for managing a

Art Unit: 3626

blood component collection facility comprising a blood component collection instrument and a system server, the system server having a memory and being operably connected to the blood component collection instrument, the blood component collection instrument being capable of self-configuring the blood component collection instrument in response to a nomogram received by the system server, the nomogram being calculated in response to a biological characteristic of an identified donor, the medium comprising:

- (5) a fourth segment for determining if a scanned identification code associated with a blood component collection kit is compatible with the selected blood component collection application (Stevens: col. 4, line 63- col. 5, line 17).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Stevens with the combined teachings of Fletcher-Haynes and Official Notice with the motivation of ensuring that compatible materials are utilized for a particular blood collection procedure.

### ***Response to Arguments***

5. Applicant's arguments with respect to claims 39-47 have been considered but are moot in view of new ground(s) of rejection.



**Conclusion**

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MT



*Carolyn Bleck*  
Patent Examiner  
9/5/06